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Sheet	1	of	9	
<b>Attorney Docket Number</b> <b>US 1292/01 (VA)</b>				

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				Application Number	09/972,916	
				Filing Date	October 10, 2001	
				First Named Inventor	Peter M. THULÉ, M.D.	
				Group Art Unit	4014 (635)	
				Examiner Name	Angell	
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		Thulé, P. M. and Liu, J., <u>Glucose Regulated Hepatic Production of Human Insulin Ameliorates Hyperglycemia in Streptozotocin Treated Rats</u> . Presented at the American Society of Gene Therapy, 2 <sup>nd</sup> Annual Meeting, Washington, D.C., June 9-13, 1999, 1 page.	
		Thulé, P. M. and Liu, J., <u>Glucose-regulated human insulin production from hepatocytes in STZ-treated rats: a model of insulin gene therapy</u> . Presented at 59 <sup>th</sup> Annual Meeting, American Diabetes Association, June 19-22, 1999, published as Supplement to Diabetes, May 1999, 1 page.	
		Thulé, P. M. and Liu, J., <u>Regulated Production of Insulin from Hepatocytes in Primary Cultures</u> . Oral Presentation, American Diabetes Associated, 58 <sup>th</sup> Annual Scientific Sessions, Chicago, Illinois, June 1998, 1 page.	
		Thulé, P. M. <u>Glucose-Regulated Human Insulin Production from Hepatocytes in STZ-Treated Rats: A Model of Insulin Gene Therapy</u> . Diabetes 48 Supplement (1): A0246, June 19-22, 1999.	
		Thulé, P. M. and Liu, J., <u>Regulated Production of Insulin from Hepatocytes in Primary Cultures</u> , Diabetes 47 Supplement (1): A0263, June 13-16, 1998.	
		Thulé, P. M., Liu, J. and Phillips, L. S. <u>Glucose Regulated Production of Human Insulin in Rat Hepatocytes</u> , submitted to Journal of Biological Chemistry (Jan. 1999), but rejected.	
		Thulé, P. M., Liu, J. and Phillips L. S. <u>Glucose regulated production of human insulin in rat Hepatocytes</u> , Gene Therapy 2000, 7(3):205-214.	
		Thulé, P. M. and Liu, J., <u>Regulated hepatic insulin gene therapy of STZ-diabetic rats</u> , Gene Therapy 2000, 7:1744-1752.	

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Filing Date	October 10, 2001
First Named Inventor	Peter M. THULÉ, M.D.
Group Art Unit	4614 1635
Examiner Name	ANGELL
Attorney Docket Number	US 1292/01 (VA)

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		Eisenbarth GS. Type I diabetes mellitus: <u>A chronic autoimmune disease</u> . N Engl J Med 1986; 314:1360-1368.	
		Falqui L, Martinenghi S, Severini GM, et al. <u>Reversal of diabetes in mice by implantation of human fibroblasts genetically engineered to release mature human insulin</u> . Human Gene Therapy 1999; 10:1753-1762.	
		Muzzin P, Eisensmith RC, Copeland KC, Woo SLC. <u>Hepatic insulin gene expression as treatment for Type 1 diabetes mellitus in rats</u> . Mol Endo 1997; 11(6):833-837	
		Gros L, Riu E, Montoliu L, Ontiveros M, Lebrigand L, Bosch F. <u>Insulin production by engineered muscle cells</u> . Human Gene Therapy 1999; 10:1207-1217.	
		Short DK, Okada S, Yamauchi K, Pessin JE. <u>Adenovirus-mediated transfer of a modified human proinsulin gene reverses hyperglycemia in diabetic mice</u> . American Journal of Physiology 1998; 275:E748-E756.	
		Rivera VM, Wang W, Wardwell S, et al. <u>Regulation of protein secretion through controlled aggregation in the endoplasmic reticulum</u> . Science 2000; 287:826-830.	
		Selden RF, Skoskiewicz MJ, Russell PS, Goodman HM. <u>Regulation of insulin-gene expression</u> . N Engl J Med 1987; 317:1067-1076.	
		Kolodka TM, Finegold M, Moss L, Woo SLC. <u>Gene therapy for diabetes mellitus in rats by hepatic expression of insulin</u> . Proc Natl Acad Sci USA 1995; 92:3293-3297.	
		Tuch BE, Tabiin MT, Casamento FM, Simpson AM, Marshall GM. <u>Transplantation of genetically engineered insulin-producing Hepatocytes into immunoincompetent mice</u> . Transplantation Proceedings 1998; 30:473.	
		Valera A, Fillat C, Costa C, et al. <u>Regulated expression of human insulin in the liver of transgenic mice corrects diabetic alterations</u> . FASEB J 1994; 8(6):440-447.	
		Kaneda Y, Iwai K, Uchida T. <u>Introduction and expression of the human insulin gene in adult rat liver</u> . Journal of Biological Chemistry 1989; 264(21):12126-12129.	

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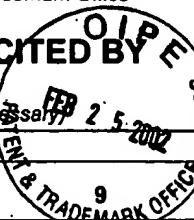
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		Yamaguchi M, Kuzume M, Matusumoto T, et al. <u>Insulin gene transfer compensates pancreatic β-cell function in diabetic rats</u> . Transplantation Proceedings 1998; 30:2913.	
		Sugiyama A, Hattori S, Tanaka S, et al. <u>Defective adenoassociated viral-mediated transfection of insulin gene by direct injection into liver parenchyma decreases blood glucose of diabetic mice</u> . Hormone and Metabolic Research 1997; 29(12):599-603.	
		Abai A, Hobart P, Barnhart KM. <u>Insulin Delivery with Plasmid DNA</u> . Human Gene Therapy 1999; 10:2637-2649.	
		Lu D, Tamemoto H, Shibata H, Saito I, Takeuchi T. <u>Regulatable production of insulin from primary-cultured hepatocytes: insulin production is up-regulated by glucagon and cAMP and down-regulated by insulin</u> . Gene Therapy 1998; 5(7):888-895.	
		Gros L, Montoliu L, Riu E, Lebrigand L, Bosch F. <u>Regulated production of mature insulin by non-b-cells</u> . Human Gene Therapy 1997; 8(18):2249-2259.	
		Wanke IE, Wong NC. <u>Specific problems facing gene therapy for insulin-dependent diabetes mellitus: glucose-regulated insulin secretion from hepatocytes</u> . Proceeding of the Western Pharmacology Society 1997; 40:131-133.	
		Simpson AM, Marshall GM, Tuch BE, et al. <u>Gene therapy of diabetes: glucose-stimulated insulin secretion in a human hepatoma cell line (HEP G2ins/g)</u> . Gene Therapy 1997; 4:1202-1215.	
		Powell DR, Suwanichkul A, Cubbage M, Lee PDK. <u>Regulation of insulin-like growth factor binding protein-1 (IGFBP-1) protein levels, mRNA levels and promoter activity by insulin (IN) and IGF-1 in HepG2</u> . Endo Society 1990:280A.	
		Powell DR, Suwanichkul A, Cubbage ML, DePaolis LA, Snuggs MB, Lee PDK. <u>Insulin inhibits transcription of the human gene for insulin-like growth factor-binding protein-1</u> . Journal of Biological Chemistry 1991; 266:18868-18876.	
		Powell DR, Suwanichkul A. <u>HNF1 activates transcription of the human gene for insulin-like growth factor binding protein-1</u> . DNA and Cell Biology 1993; 12:283-289.	
		Suwanichkul A, Cubbage ML, Powell DR. <u>The promoter of the human gene for insulin-like growth factor binding protein-1. Basal promoter activity in HEP G2 cells depends upon liver factor B1</u> . Journal of Biological Chemistry 1990; 265:21185-21193.	

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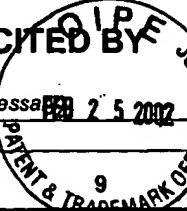
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Application Number **09/972,916**  
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 First Named Inventor **Peter M. THULÉ, M.D.**  
 Group Art Unit **1614 (635)**  
 Examiner Name **Angele**  
 Attorney Docket Number **US 1292/01 (VA)**

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		Swanichkul A, DePaolis LA, Lee PDK, Powell DR. <u>Identification of a promoter element which participates in cAMP-stimulated expression of human insulin-like growth factor-binding protein-1</u> . Journal of Biological Chemistry 1993; 268:9730-9736.	
		Swanichkul A, Morris SL, Powell DR. <u>Identification of an insulin-responsive element in the promoter of the human gene for insulin-like growth factor binding protein-1</u> . Journal of Biological Chemistry 1993; 268:17063-17068.	
		Swanichkul A, Allander SV, Morris SL, Powell DR. <u>Glucocorticoids and insulin regulate expression of the human gene for insulin-like growth factor-binding protein-1 through proximal promoter elements</u> . Journal of Biological Chemistry 1994; 269:30835-30841.	
		Hughes SD, Johnson JH, Quaade C, Newgard CB. <u>Engineering of glucose-stimulated insulin secretion and biosynthesis in non-islet cells</u> . 1992; 89:688-692.	
		Rencurel F, Waever G, Antoine B, et al. <u>Requirement of glucose metabolism for regulation of glucose transporter type 2 (GLUT 2) gene expression in liver</u> . Biochemical Journal 1996; 314:903-909.	
		Villafruente BC, Goldstein S, Murphy LJ, Phillips LS. <u>Nutrition and Somatomedin XXV. Regulation of insulin-like growth factor binding protein-1 in primary cultures of normal rat hepatocytes</u> . Diabetes 1991; 40:837-841.	
		Ooi GT, Tseng LY-H, Tran MQ, Rechler MM. <u>Insulin rapidly decreases insulin-like growth factor-binding protein-1 gene transcription in streptozotocin-diabetic rats</u> . Molecular Endocrinology 1992; 6:2219-2228.	
		Pao C-I, Farmer PK, Begovic S, Goldstein S, Wu G-J, Phillips LS. <u>Expression of hepatic insulin-like growth factor-I and insulin-like growth factor-binding protein-1 genes is transcriptionally regulated in streptozotocin-diabetic rats</u> . Molecular Endocrinology 1992; 6:969-977.	
		Suh D-S, Zhou Y, Ooi GT, Rechler MM. <u>Dexamethasone stimulation of rat insulin-like growth factor binding protein-1 (IGFBP-1) promoter activity involves the interaction of multiple transcription factors</u> . Progress in Growth Factor Research 1995; 6:131-140.	
		Cuif M-H, Cognet M, Boquet D, Tremp G, Kahn A, Vaulont S. <u>Elements responsible for hormonal control and tissue specificity of L-type pyruvate kinase gene expression in transgenic mice</u> . Molecular and Cellular Biology 1992; 12:4852-4861.	
		Cognet M, Lone YC, Vaulont S, Kahn A, Marie J. <u>Structure of the rat L-type pyruvate kinase gene</u> . J Mol Biol 1987; 196:11-25.	

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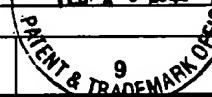
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First Named Inventor	Peter M. THULÉ, M.D.
Group Art Unit	1644-1635
Examiner Name	Angell
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		Bergot M-O, Diaz-Guerra M-JM, Puzenat N, Raymondjean M, Kahn A. <u>Cis-regulation of the L-type pyruvate kinase gene promoter by glucose, insulin and cyclic AMP</u> . Nucleic Acids Research 1992; 20(8):1871-1878.	
		Vaulont S, Munnich A, Decauz J-F, Kahn A. <u>Transcriptional and post-transcriptional regulation of L-type pyruvate kinase gene expression in rat liver</u> . Journal of Biological Chemistry 1986; 261:7621-7625.	
		Goswami R, Lacson R, Unterman T. <u>Identification of insulin and glucocorticoid response sequences in the rat IGF binding protein-1 (IGFBP-1) promoter</u> . Endocrine Society 1993; 1915B:529.	
		Shu D-S, Ooi GT, Lesniak MAS. <u>Inhibition of IGFBP-1 gene expression by insulin and stimulation by dexamethasone, cyclic AMP, and phorbol esters are mediated by different cis-acting elements in the rat IGFBP-1 promoter</u> . Endocrine Society 1993; 1916B:529.	
		Smeekens SP, Chan SJ, Steiner DF. <u>The biosynthesis and processing of neuroendocrine peptides: identification of proprotein convertases involved in intravesicular processing</u> . Progress in Brain Research 1992; 92:235-246.	
		Groskreutz DJ, Sliwkowski MX, Gorman CM. <u>Genetically engineered proinsulin constitutively processed and secreted as mature, active insulin</u> . Journal of Biological Chemistry 1994; 269(8):6241-6245.	
		Steiner DF, Smeekens SP, Ohagi S, Chan SJ. <u>The New Enzymology of Precursor Processing Endoproteases</u> . Journal of Biological Chemistry 1992; 267:23435-23438.	
		Simonson GD, Groskreutz DJ, Gorman CM, MacDonald MJ. <u>Synthesis and processing of genetically modified human proinsulin by rat myoblast primary cultures</u> . Human Gene Therapy 1996; 7:71-78.	
		Unger RH, Foster DW. Chapter 21. In: Wilson JD, Foster DW, Kronenberg HM, Williams RH, eds. <u>Williams Textbook of Endocrinology</u> . Vol. 9th. Philadelphia, London, Toronto, Montreal, Sydney: W.B Saunders Co., 1998:973-1059.	
		Robertson DG, Marino EM, Thule PM, Seneviratne CK, Murphy LJ. <u>Insulin and glucocorticoids regulate IGFBP-1 expression via a common promoter region</u> . Biochemical Biophysical Research Communications 1994; 200(1):226-232.	
		Goswami R, Lacson R, Yang E, Sam R, Unterman T. <u>Functional analysis of glucocorticoid and insulin response sequences in the rat insulin-like growth factor-binding protein-1 promoter</u> . Endocrinology 1994; 134:736-743.	

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		Goldstein S, Sertich G, Levan KR, Phillips LS. <u>Nutrition and somatomedin. XIX. Molecular regulation of insulin-like growth factor-I in streptozotocin-diabetic rats.</u> Molecular Endocrinology 1988; 2:1093-1100.	
		Minematsu S, Watanabe M, Tsuchiya N, Amagaya S. <u>Diurnal variations in blood chemical items in Sprague-Dawley rats.</u> Experimental Animals 1995; 44:223-232.	
		Haughton CL, Dillehay DL, Phillips LS. <u>Insulin replacement therapy for the rat model of streptozotocin-induced diabetes mellitus.</u> Laboratory Animal Science 1999; 49:639-644.	
		Koopmans SJ, Sips HCM, Krans HMJ, Radder JK. <u>Pulsatile intravenous insulin replacement in streptozotocin-diabetic rats is more efficient than continuous delivery: effects on glycaemic control, insulin-mediated glucose metabolism and lipolysis.</u> Diabetologia 1996; 39:391-400.	
		Wang RN, Bouwens L, Kloeppel G. <u>Beta-cell proliferation in normal and streptozotocin-treated newborn rats: site, dynamics and capacity.</u> Diabetologia 1994; 37:1088-1096.	
		Like AA, Guberski DL, Butler L. <u>Influence of Environmental Viral Agents on Frequency and Tempo of Diabetes Mellitus in BB/Wor Rats.</u> Diabetes 1991; 40:259-262.	
		Seglen PO. <u>Preparation of rat liver cells. III. Enzymatic requirements for tissue dispersion.</u> Exp Cell Res 1973; 82:391-398.	
		Ginot F, Decaux J-F, Cognet M, et al. <u>Transfection of hepatic genes into adult rat hepatocytes in primary culture and their tissue-specific expression.</u> Eur J Biochem 1989; 180:289-294.	
		Baker A, Saltik M, Lehrmann H, et al. <u>Polyethylenimine (PEI) is a simple, inexpensive and effective reagent for condensing and linking plasmid DNA to adenovirus for gene delivery.</u> Gene Therapy 1997; 4:773-782.	
		Marriott D, Gillice-Castro B, Gorman CM. <u>Prohormone convertase-1 will process prorelaxin, a member of the insulin family of hormones.</u> Molecular Endocrinology 1992; 6:1441-1450.	

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		Mittereder N, March KL, Trapnell BC. <u>Evaluation of the concentration and bioactivity of adenovirus vectors for gene therapy</u> . Journal of Virology 1996; 70:7498-7509.	
		Alam T. <u>Reduction in diabetic hyperglycemia by glucose-regulated insulin release from transduced hepatocytes</u> . University of Wisconsin Department of Surgery (Undated). (4 pages) Web site: <a href="http://www.surgery.wisc.edu/research/txlab_ta-rotrf.html">http://www.surgery.wisc.edu/research/txlab_ta-rotrf.html</a> .	
		Bloomgarden, Z. <u>New approaches to insulin treatment and glucose monitoring</u> . (American Diabetes Association Annual Meeting, 1999. Diabetes care 22(12):2078. (13 pages)	
		Ferber S, Halkin A, Cohen H, Ber I, Einav Y, Goldberg I, Barshack I, Seijffers R, Kopolovic J, Kaiser N, Karasik A. <u>Pancreatic and duodenal homeobox gene 1 induces expression of insulin genes in liver and ameliorates streptozotocin-induced hyperglycemia</u> . Nature medicine May 2000; 6(5):568-572.	
		Institute of Human Gene Therapy, University of Pennsylvania Health System. <u>Prospects in gene therapy</u> . March 11, 1999. (4 pages) Web site: <a href="http://med.upenn.edu/ihgt/info/prospects.html">http://med.upenn.edu/ihgt/info/prospects.html</a> .	
		Leibiger B, Moede T, Schwarz T, Brown G.R., Köhler M, Leibiger I.B., Berggren, P-O. <u>Short-term regulation of insulin gene transcription by glucose</u> . Proceedings of the National Academy of Sciences 1998; 95(16):9307-9312.	
		National Institutes for Diabetes & Digestive & Kidney Diseases. <u>Diabetes statistics</u> . National Diabetes Information Clearinghouse, NIH Publication No. 99-3892, March 1999. (11 pages) Web site: <a href="http://www.niddk.nih.gov/health/diabetes/pubs/dmstats/dmstats.htm#what">http://www.niddk.nih.gov/health/diabetes/pubs/dmstats/dmstats.htm#what</a> .	
		Osborne W, Barry, S. <u>Glucose-regulated insulin expression in diabetic rats</u> . Molecular therapy May 2000; 1(5):S27-S31. (2 pages)	
		Rajan, A. <u>An update on islet cell replacement</u> . American Diabetes Association's 59 <sup>th</sup> Scientific Session, Day 4, June 22, 1999. (6 pages) Web site: <a href="http://www.islet.org/forum/messages/8637.htm">http://www.islet.org/forum/messages/8637.htm</a> .	

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<b>LIST OF PRIOR ART CITED BY APPLICANT</b> <i>(use as many sheets as necessary)</i>			Application Number	09/972,916
			Filing Date	October 10, 2001
			First Named Inventor	Peter M. THULÉ, M.D.
			Group Art Unit	4014-1636
			Examiner Name	Angela
Sheet	9	of	Attorney Docket Number	US 1292/01 (VA)

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<i>S</i>		Simpson AM, Tuch BE, Swan MT, Tu J, Marshall GM. <u>Functional expression of the human insulin gene in a human hepatoma-cell line (hep_g2)</u> . Gene therapy 1995; 2(3):223-231.	
<i>S</i>		Tomita N, Oghihara T, Kondo T, Kanyeda Y. <u>A novel gene-transfer technique mediated by HVJ (Sendai virus), nuclear-protein and liposomes</u> . Cancer detection and prevention 1994; 18(6):485-491.	
<i>NO X DATE</i>		Wanke I. <u>Diabetes scene - gene therapy for diabetics?</u> (1 page) Web site: <a href="http://www.banting.com/tcenter/gene.html">http://www.banting.com/tcenter/gene.html</a> .	
<i>NO X DATE</i>		Woo S, Lernmark A. <u>Gene therapy approaches for diabetes and its complications: summary and recommendations</u> . NIDDK Conference Reports and Archives, November 8-9, 1999. (5 pages) Web site: <a href="http://www.niddk.nih.gov/fund/reports/gene_therapy_summ.htm">http://www.niddk.nih.gov/fund/reports/gene_therapy_summ.htm</a> .	
<i>NO X DATE</i>		Zhdanov, R. <u>Laboratory of Gene Therapeutics</u> . Institute of Biochemical Chemistry, Russian Academy of Medical Sciences. (7 pages) Web site: <a href="http://www.ibmh.msk.su/depart/gene.htm">http://www.ibmh.msk.su/depart/gene.htm</a> .	
<i>NO X DATE</i>		<u>Impact of Diabetes</u> . (2 pages) Web site: <a href="http://www.diabetesinstitute.org">http://www.diabetesinstitute.org</a>	
<i>NO X DATE</i>		<u>Background on Diabetes</u> . (3 pages) Web site: <a href="http://www.diabetesinstitute.org">http://www.diabetesinstitute.org</a>	
<i>NO X DATE</i>		Woo S., Professor and Director, Institute for Gene Therapy and Molecular Medicine, Professor, Department of Human Genetics, Mount Sinai School of Medicine, New York, New York. (3 pages)	

\* NOTE. References crossed out not considered because NO DATE is given; as required

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